Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bupivacaine Hydrochloride is and what it is used for

Bupivacaine Hydrochloride contains the active substance bupivacaine hydrochloride. It belongs to a group of medicines called amide-type local anaesthetics. It produces a loss of feeling or sensation that is confined to one part of the body.

Bupivacaine Hydrochloride is used to numb (anaesthetise) parts of the body. It is used to stop pain happening or to provide pain relief. It can be used to:

- numb parts of the body during surgery in adults and children above 12 years
- relieve pain in adults, infants and children above 1 year of age
- surgical operations, including obstetric operations such as caesarean section
- relief of acute pain including labour pain or pain after an operation

You must talk to your doctor if you do not feel better or if you feel worse after (number of) days.

2. What you need to know before you use Bupivacaine Hydrochloride

Do not use Bupivacaine Hydrochloride:

- If you are allergic to bupivacaine hydrochloride or to any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine or ropivacaine).
- If you have a skin infection near to where the injection will be given.
- If you have something called cardiacogenic shock (a condition where the heart is unable to supply enough blood to the body).
- If you have something called hypovolaemic shock (very low blood pressure leading to inadequate blood supply to the body).
- If you have problems with clotting of your blood.
- If you have diseases of the brain or spine such as meningitis, polio or spondylitis.
- If you have a neurosurgical headache caused by bleeding inside the head (intracranial haemorrhage).
- If you have problems with your spinal cord due to anaemia.
- If you have blood poisoning (sepsicaemia).
- If you have a recent trauma, tuberculosis or tumours of the spine.
- If you are having obstetrical paracervical block (a type of infiltration during labour).
- Adhesive containing bupivacaine for special techniques (e.g. perineal block, Gebert block) to numb parts of the body where areas with end arteries are affected.

You must not be given Bupivacaine Hydrochloride if any of the above apply to you. If you are not sure, talk to your doctor before you are given Bupivacaine solution for injection.

The following information is intended for healthcare professionals only.

Any unused solution should be adequately disposed of, in accordance with local requirements.

1. Administration

Solution for injection.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Bupivacaine Hydrochloride:

- If you are elderly and are in a generally impaired condition.
- If you have any heart, liver or kidney problems. This is because your doctor may need to adjust the dose of Bupivacaine Hydrochloride.
- If you have a seeped stomach due to more fluid than normal.
- If you have a stomach tumour.
- If you have been told that you have decreased volume of blood (hypovolaemia) if you have fluid in your lungs.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection (an injection around the spinal cord).
- If you have a severe headache caused by bleeding inside the head (intracranial haemorrhage).
- If you have been given Bupivacaine solution for injection.
- If you have any heart, liver or kidney problems. This is because the volume of blood is important in calculating the required dose. The lowest dose required for adequate anaesthesia should be used. An overall dose limit of 150 mg should not be exceeded. A dose of 400 mg administered over 24 hours is well tolerated in the average adult.

Children

In children under 12 years as injections of Bupivacaine Hydrochloride in order to numb parts of the body during surgery are not established in younger children Bupivacaine Hydrochloride is not established in children < 1 year.

If you are not sure if any of the above apply to you, talk to your doctor before you are given Bupivacaine Hydrochloride.

Other medicines and Bupivacaine Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking some medicines together can be harmful. Remember that the doctor at the hospital may not have informed you recently begun a course of treatment for another illness. In particular tell your doctor if you are taking:

- medicines to control your heartbeat (such as lidocaine, mexiletine, or amiodarone)
- Medicines used to stop blood clots (anti-coagulants). Your doctor needs to know about these medicines to be able to work out the correct dose of Bupivacaine Hydrochloride for you.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Bupivacaine may get into breast milk. If you are breast-feeding you should discuss options with your doctor.

Driving and using machines

Bupivacaine hydrochloride may make you feel sleepy and affect the speed of your reactions. After you have been given Bupivacaine Hydrochloride, you should not drive or use tools or machines until the next day.

Bupivacaine Hydrochloride contains Sodium Each ml of Bupivacaine 2.5 mg/ml injection contains approximately 3.38 mg (0.15 mmol) of sodium. Each ml of Bupivacaine 5 mg/ml injection contains approximately 6.73 mg (0.35 mmol) of sodium. To be taken into consideration by patients on a controlled sodium diet.

How to store Bupivacaine Hydrochloride

Bupivacaine Hydrochloride will be given to you by your doctor who will have the necessary knowledge and experience in the technique of epidural anaesthesia.

The recommended dose that your doctor gives you will depend on the type of pain relief that you need and the part of your body that the medicine will be injected into. It will also depend on your body size, age, and physical condition. Usually one dose will last long enough but more doses may be given if the surgery takes a long time.

Bupivacaine Hydrochloride will be given to you as an injection. The part of the body where you are injected will depend on why you are being given Bupivacaine Hydrochloride. Your doctor will give you Bupivacaine hydrochloride in one of the following places:

- Near to the part of the body that needs to be numbed.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection (an injection around the spinal cord).

When Bupivacaine Hydrochloride is injected into the body in one of these ways, it stops the nerves from being able to pass pain messages to the brain. It will slowly wear off when the medical procedure is over.

Method of administration

The medicinal product is for percutaneous infiltration, peripheral nerve block(s) and central neuraxial block (caudal or epidural) use only.

The medicinal product is for percutaneous infiltration, peripheral nerve block(s) and central neuraxial block (caudal or epidural) use only. This is because the doctor may need to adjust the dose of Bupivacaine Hydrochloride. If the clinician is expecting the patient’s physical status is important in calculating the required dose. The lowest dose required for adequate anaesthesia should be used. An overall dose limit of 150 mg should not be exceeded. A dose of 400 mg administered over 24 hours is well tolerated in the average adult. For the paediatric patient’s lowest dose required for adequate anaesthesia should be used.
If you take more Bupivacaine Hydrochloride than you should
Serious side effects from getting too much Bupivacaine
Hydrochloride are unlikely. They need special treatment and the
doctor treating you is trained to deal with these situations. The first
signs of being given too much Bupivacaine Hydrochloride are usually
as follows:
• Feeling dizzy or light-headed
• Numbness of the lips and around the mouth.
• Numbness of the tongue.
• Hearing problems.
• Problems with your sight (vision).
To reduce the risk of serious side effects, your doctor will stop giving
you Bupivacaine Hydrochloride as soon as these signs appear.
This means that if any of these happen to you, or you think you
have received too much Bupivacaine Hydrochloride, tell your doctor
immediately.
More serious side effects from being given too much Bupivacaine
Hydrochloride include:
• Twitching of your muscles.
• Double vision.
• Numbness of the tongue.
• Damaged nerves. Rarely this may cause permanent problems.
• Blindness which is not permanent or problems with the muscles
of the eyes that are long-lasting. This may happen with some
injections given around the eyes.

Additional side effects in children and adolescents
Adverse drug reactions in children are similar to those in adults.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse.
This includes any possible side effects not listed in this leaflet. You
may also report side effects directly via Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard. By reporting side effects you can help
provide more information on the safety of this medicine.

5. How to store Bupivacaine Hydrochloride
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the
ampoule, vial and carton after EXP. The expiry date refers to the last
day of that month.
Do not use this medicine if you notice the contents are discoloured
in any way or if particles are present.
Bupivacaine Hydrochloride is for single use only. Discard any unused
solution.
This medicinal product does not require any special storage conditions.
Do not throw away any medicines via wastewater or household
waste. Ask your pharmacist how to throw away medicines you no
longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Bupivacaine Hydrochloride contains
– The active substance is bupivacaine hydrochloride.
Bupivacaine Hydrochloride 5 mg/ml:
Each ampoule contains 2.5 mg of bupivacaine hydrochloride
Each ampoule contains 25 mg of bupivacaine hydrochloride.
Bupivacaine Hydrochloride 5 mg/ml:
Each ampoule contains 5 mg of bupivacaine hydrochloride.

– The other ingredients are Sodium chloride, sodium hydroxide
(pH adjustment), hydrochloric acid (pH adjustment) and water for
injection.

What Bupivacaine Hydrochloride looks like and contents of the pack
Solution for injection
A clear, colourless, aqueous, sterile solution.
10 ml type I clear glass ampoules
Each carton contains 1, 5, 10, 20 and 100 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milibhan Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HDG, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBQ 3000
Malta

Or
Milibhan Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This leaflet was last revised in 11/2016.

Storage information
This medicinal product does not require any special storage conditions.